UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS	)	Chief Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES, INC.'S MEMORANDUM IN OPPOSITION TO UNITED STATES' AND RELATOR'S MOTION FOR A COMPREHENSIVE CASE MANAGEMENT ORDER

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PRELIMINARY STATEMENT

Plaintiffs seek hundreds of millions of dollars based on the contention that the Government relied on published drug prices as a reasonable proxy for market prices. Plaintiffs claim that "[n]o government payor knew of or sanctioned Abbott's conduct as set forth in this Complaint" (Complaint, ¶ 38) and that the Government learned only in "hindsight" about drug spreads. Brief of United States as Amicus Curiae ("U.S. Amicus") at 2. Yet the United States now complains that any discovery seeking to challenge that assertion is "irrelevant" and overly burdensome. Plaintiffs' own filings and the very elements of Plaintiffs' causes of action make clear that this one-sided view is wrong. In truth, Plaintiffs are trying to limit Abbott's ability to develop a record that will refute Plaintiffs' theories and show the real reasons why the Federal and State Governments chose to base reimbursement on prices published by compendia.

Plaintiffs' motion and memorandum conflate two separate discovery issues: (1) The parties' disagreements on the appropriate length and limits of discovery; and (2) Plaintiffs' effort to ignore well-established rules for responding to discovery and to hide damaging evidence about "government knowledge" from discovery. Only the first of these issues warrants intervention from this Court. For the reasons discussed below, Abbott respectfully requests that the Court:

- Enter Abbott's Proposed Case Management Order No. 1, attached as Exhibit 1;
- Order the parties to respond to outstanding discovery within 14 days; and
- Deny Plaintiffs' premature and baseless request to bar discovery of relevant information, including on the subject of "government knowledge."

ARGUMENT

I. PLAINTIFFS' PROPOSED DISCOVERY SCHEDULE AND LIMITS ARE INAPPROPRIATE FOR THIS CASE.

After having over ten years to pursue evidence in support of their claims, Plaintiffs now propose a CMO with unduly restrictive and inappropriate limits on Abbott's discovery efforts.

This Court should reject those limits in favor of the more reasonable provisions contained in Abbott's proposed CMO. The following are the major points of disagreement between the parties on the appropriate length and limits of discovery.

1. Applicability of CMO to All Defendants. Plaintiffs' proposed CMO would apply not only to its case against Abbott, but also "to any other parties in lawsuits that are consolidated with this proceeding in which the United States is a party." Plfs. Prop. CMO ¶ 1. Plaintiffs' proposed CMO seeks to establish pre-determined discovery limits upon an undetermined number of defendants. *See id*. ¶ 3. For example, Plaintiffs' proposed CMO states that "Abbott shall share and coordinate deposition hours with other defendants including any defendants to future lawsuits by the United States that join this MDL proceeding." *Id*. ¶ 11. Plaintiffs' approach is unworkable and unfair to Abbott.

It is not feasible to establish joint discovery limits upon all defendants when the United States has not yet revealed how many defendants would share those limits. Instead of pre-judging that issue, discovery limits and scheduling matters for any other cases brought by the United States should be determined on a case-by-case basis, giving each future defendant an opportunity to be heard. Abbott's proposed CMO is properly confined to this case, the only context in which the appropriateness of discovery limits can be reasonably evaluated. Abbott Prop. CMO ¶ 1.

2. Duration of Fact Discovery. Fact and expert discovery should be completed in one year. Abbott Prop. CMO ¶ 5. For almost ten years, Plaintiffs have subpoenaed from Abbott and third parties the documents they need to pursue their claims. If Plaintiffs respond promptly to the discovery propounded by Abbott, one year of discovery should suffice. Prior experience in these AWP cases teaches that plaintiffs leave the answers to many important questions to their experts. Abbott should not be forced to wait 18 months before getting those answers. Plaintiffs

propose 18 months for fact discovery and another three months for expert disclosures and depositions. Such a long discovery period is unnecessary, particularly since Plaintiffs have had over ten years to investigate their claims. Assuming 160 hours of working time per month, 21 months equates to 3360 hours of working time *per lawyer*. The parties do not need that much time to utilize even the 500 hours of deposition time proposed by Abbott.

3. Depositions. Plaintiffs now propose that "each side" be permitted only 250 hours of deposition time. Plfs. Prop. CMO ¶¶ 3, 11. Even when Plaintiffs wanted to limit Abbott alone to 250 hours, the provision paled in comparison to the deposition time used in individual state cases. Now it is plainly absurd. For example, in an AWP case brought in Texas by Relator Ven-A-Care of the Florida Keys, Inc. (the Relator in this case) against another manufacturer, the parties took over 120 depositions before settling the case. That case involved only one state, only one defendant, and only the Texas Medicaid program. This case involves nearly every state, plus the entire federal Medicare program, and a ten-year period for which the Government seeks supposed damages (1991-2001).

Abbott proposes 500 hours of deposition time for Plaintiffs and 500 hours for Abbott. Abbott Prop. CMO ¶ 6. Abbott's analysis of documents and data indicate that extensive deposition time will be necessary to unravel the flaws in Plaintiffs' claims. For example, Abbott's review of the Medicaid utilization data produced by Plaintiffs suggests that many state Medicaid programs did not reimburse drugs according to the published formulae. Thus, a state whose formula may suggest reimbursement at AWP–10% may have actually paid closer to AWP–50% or, in many cases, even less. Many possible reasons exist for such a discrepancy,

and Abbott will need significant deposition time to sort out this important information.[1]

Plaintiffs also have proposed limiting the duration of any fact deposition under Rule 30(b)(1) to one seven-hour day. Plfs. Prop. CMO ¶ 11.C. By contrast, MDL 1456's CMO No. 10 provides: "No deposition of a witness by a deposing party shall be longer than twenty-one hours unless agreed by the party or permitted by court order. The non-deposing party shall have seven hours for cross-examination. There shall be two hours for re-direct and two hours for re-cross." CMO No. 10 ¶ II.8. Because many key federal officials (who were involved in both the Medicare and Medicaid programs) are likely to be deposed, Plaintiffs' proposal is insufficient. Abbott proposes a middle ground: fact depositions should be limited to 14 hours of questioning for the noticing party and seven hours for all non-noticing parties, inclusive of any re-direct or re-cross examination. Abbott Prop. CMO ¶ 8(a).

4. Requests for Admission. Abbott opposes any limitation on the number of Requests for Admission ("RFAs"), as these Requests are badly needed to narrow the issues in this complex case. Abbott Prop. CMO ¶ 6. Plaintiffs, however, seek a limit of 50 and attack Abbott's first round of RFAs as inappropriate.

The parties have a fundamental difference of opinion regarding the purpose of RFAs. Plaintiffs argue that "Rule 36 does not contemplate requests for admission directed at disputed facts." Plfs. CMO Br. at 14. To the contrary, that is the purpose for such requests – to determine whether facts are in dispute and to avoid unnecessary discovery expense and trial time. Indeed, Rule 36 expressly provides that "[a] party who considers that a matter of which an admission has

[1] One example is the state of Washington's implementation of an "automatic maximum allowable cost" provision during the relevant claim period which automatically set reimbursement for multiple-source drugs at the third lowest priced drug for any drug within a generic drug sequence. *See* HHC020-1719, HHC020-1723-26 (Ex. 2). (Copies of materials cited herein have been electronically filed concurrently herewith at the indicated Exhibit ("Ex.") numbers.) Because such provisions would mean that Medicaid's reimbursement was not based upon published prices, their existence would contradict Plaintiffs' theories of liability and damages.

been requested presents a genuine issue for trial may not, on that ground alone, object to the request." Fed. R. Civ. P. 36(a).[2]

Abbott's RFAs are not improper "contention interrogatories," nor do they "request Plaintiffs to state the truth of a legal conclusion." Plfs. CMO Br. at 14-15. Contention interrogatories typically request a party to provide all evidence in support of a particular contention. The RFAs identified as "improper" on this ground do nothing more than ask the Government to take a position on important issues. Such RFAs concern the application of law to fact and are appropriate.

Abbott's RFAs also do not ask for legal conclusions. For example, the request for Plaintiff to admit that the "term 'Average Wholesale Price' or 'AWP' is not defined in any federal statute or regulation" (RFA 1) raises a factual question: Did a federal statute or regulation exist that defined AWP? It is a yes or no question. That a request concerns a statute or regulation (or, in this case, the lack of one) does not render it a request for a legal conclusion.

Plaintiffs also complain about RFAs regarding the truth of "quoted text within documents." Plfs. CMO Br. at 15. These requests, however, are proper and highly probative. *See Mitchell v. Beaubouef*, 581 F.2d 412, 415 (5th Cir. 1978) (party may authenticate state actor's documents through RFA). For example, Abbott has posed the following RFA:

> 267. In a written response to a question posed by Senator Orrin Hatch during deliberations on the 1997 BBA, Secretary Donna Shalala stated: "Medicare pays the [AWP] for covered drugs. However, the AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a 'sticker' price set by drug manufacturers and published in several commercial catalogs."

[2] The cases cited by Plaintiffs provide them no support. *Chicago Dist. Council of Carpenters Pension Fund v. P.M.Q.T., Inc.*, 169 F.R.D. 336, 441 (N.D. Ill. 1996), states only that a party may not factually contest matters that have already been admitted. *Burns v. Phillips*, 50 F.R.D. 187, 188-89 (N.D. Ga. 1970) and *California v. The Jules Fribourg*, 19 F.R.D. 432, 435-36 (N.D. Cal. 1955), both rely on authority predating the 1970 amendment that specifically rejected the notion that disputed facts are improper subjects for a request for admission.

RFA 267 (citing *Hearing on President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare Before the Senate Committee on Finance*, 105th Cong. 265 (1997) (Ex. 3)). If true, Plaintiffs should admit RFAs such as these and save the expense of unnecessary deposition testimony that might otherwise be needed to present undisputed facts to the jury. Much of the important evidence in this case is undisputed. Unlimited RFAs would allow the parties to get these issues out of the way and focus discovery where disputes actually exist.[3] Of course, if Plaintiffs believe particular requests are unduly burdensome or otherwise improper, they may object to those particular requests in accordance with Rule 36(a).

5. Interrogatories and Requests for Production. Abbott believed the parties had reached, or were close to reaching, agreement on limits for interrogatories (65 to 75 each) and requests for production (seven rounds each). Plaintiffs now propose, however, that these limits should apply not only to Abbott but also to any future defendants. The fact that Plaintiffs agreed to these limits when Abbott was the only manufacturer sued by the United States is proof enough that Plaintiffs believed these limits were appropriate as to Abbott. Abbott should not suffer diminishing discovery rights every time the Government adds a defendant.[4]

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[3] The number of RFAs already propounded by Abbott (298) is not excessive for this complex case. *See, e.g., Duncan v. Santaniello*, Civ. A. No. 94-030224-MAP, 1996 WL 121730,* 3 (D. Mass. Mar. 8, 1996) (holding that 322 requests for admission was not so large as to warrant a protective order preventing defendants from responding to requests); *Photon, Inc. v. Harris Intertype, Inc.*, 28 F.R.D. 327, 329 (D. Mass. 1961) (requiring plaintiff to answer majority of over 700 requests for admission, reasoning that "purely factual matters . . . will have to be resolved for the record at some time . . . and establishment of these facts through the medium of requests for admission will *pro tanto* shorten the trial").

[4] Plaintiffs' request "that Abbott not re-serve upon the United States any document requests to which the United States previously produced responsive materials" (United States' and Relator's Memorandum in Support of Their Motion for a Comprehensive Case Management Order ("Plfs. CMO Br.") at 12-13) is an improper attempt to immunize responsive documents previously withheld from discovery. Abbott is entitled to know what documents were withheld under what grounds, so that it can consider whether the United States' privilege assertions or other refusal to produce documents as a third party are appropriate here.

Abbott understands the United States may have previously produced documents responsive to Abbott's requests, and it has not asked the United States to "determine[e] which of the tens of thousands of documents it previously produced . . . match Abbott's current document requests in this case." *Id.* at 12. It appears the United States has produced these documents already in its initial disclosures anyway.

6. United States' Responsibility to Produce Responsive Documents in Possession of the "United States." Plaintiffs have proposed that "discovery directed to the 'United States'" shall pertain only to HHS and CMS. Plfs. Prop. CMO ¶ 6. This limitation is inappropriate. The United States cites no authority that allows it to restrict unilaterally the agencies from which it is obligated to search for responsive documents.[5] If there is responsive information in the possession or control of other departments or agents of the United States, the United States is obligated to produce it. Abbott has expressed its willingness to narrow the search to specified departments and carriers, but those overtures were ignored.[6] *See* Abbott Prop. CMO ¶ 4.

7. Expert Reports. Plaintiffs request the simultaneous exchange of initial expert reports. *See id*., ¶ 9. That does not make sense and is unworkable. Abbott's expert reports will, in the main, respond to Plaintiffs' expert reports, and they cannot do so until after Plaintiffs issue expert reports. Accordingly, Abbott proposes that its expert reports be due one month after Plaintiffs' reports, consistent with the practice in other MDL 1456 actions. Abbott Prop. CMO ¶ 5; *see also* CMO No. 10, ¶¶ III.10, IV.2, CMO No. 15, ¶¶ 2-3.

8. Discovery on Government Knowledge Should Not be Stayed. Plaintiffs propose that "[a]ll discovery related to any 'government knowledge' argument asserted by Abbott, or any other defendant, shall be deferred until the Court rules on Abbott's Motion to Dismiss." Plfs. Prop. CMO ¶ 7. As explained in Section III below, discovery relating to "government knowledge" is highly relevant to this litigation and should begin immediately.

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[5] The DOJ's website indicates that it represents "the United States, its departments and agencies, Members of Congress, Cabinet officers and other Federal Employees." *See* http://www.usdoj.gov/civil/home.html.

[6] *See* Letter from J. Daly to R. Brooker and M. Lavine (July 24, 2006) (Ex. 4). The Government has previously indicated that it represents Medicare carriers in AWP cases. *See* March 31, 2006 Letter from HHS Office of General Counsel to T. Tabacchi (responding to subpoena to Medicare carrier) (Ex. 5).

II. PLAINTIFFS HAVE FAILED TO MEET-AND-CONFER ON ABBOTT'S DISCOVERY REQUESTS AND THEIR OBJECTIONS ARE TOO VAGUE AND OVERREACHING TO WARRANT RELIEF.

This Court should deny out of hand Plaintiffs' attacks on Abbott's outstanding discovery requests for failure to comply with the procedural requirements applicable to all litigants. Applying for a case management order to foreclose inquiry into huge swaths of facts defeats the process by which discovery disputes are handled in federal courts every day. There is nothing unique about this case, and Plaintiffs should be required to abide by the rules.

If Plaintiffs object to a discovery request, they must assert their objections in a written response and articulate why the discovery request is irrelevant or unduly burdensome. *See* Fed. R. Civ. P. 33(b); 34(b); 36(a).[7] To the extent Abbott's requests are not objectionable, Plaintiffs must respond timely or seek an extension. For example, there can be no dispute that Abbott is entitled to the claims data it requested in its July 12, 2006 requests for production. There is no reason to withdraw that request and restart the clock.

Rather than follow the rules, Plaintiffs filed a blunderbuss motion for a "comprehensive" case management order, seeking to put all inquiry into the Government's own actions outside the "allowable scope of discovery." Plfs. CMO Mot. at 3-10. Because Plaintiffs' contentions on the allowable scope of discovery – particularly in the area of "government knowledge" – are unsupportable (*see* Section III) and inappropriate under the Federal Rules, the Court should reject Plaintiffs' request for Abbott to withdraw its discovery and order Plaintiffs to respond to each of Abbott's discovery requests within 14 days. Abbott Prop. CMO ¶ 3.

[7] Abbott will discuss reasonable modifications to outstanding discovery to prevent undue burden. For example, with respect to the Declaration of Karen Jackson (Ex. 10 to Plfs. CMO Br.) discussing the burden of searching the files of Medicare carriers, Abbott is confident the parties can agree upon a suitable subset of carriers and time periods, perhaps staging discovery as appropriate. Because they failed to meet-and-confer on this or any other discovery request, however, Plaintiffs are not aware of the compromises Abbott is willing to negotiate.

III. ABBOTT'S DISCOVERY REQUESTS ARE RELEVANT AND APPROPRIATE.

A. Legal Standard

Abbott is entitled to discovery "regarding any matter, not privileged, that is relevant to the claim or defense of any party." Fed. R. Civ. P. 26(b). Rule 26 specifically provides that "[r]elevant information need not be admissible at the trial if the discovery appears to be reasonably calculated to lead to the discovery of admissible evidence." *Id.* Relevancy must be broadly construed in the discovery context, and courts are obligated to err on the side of permitting discovery. *See Gagne v. Reddy*, 104 F.R.D. 454, 456 (D. Mass. 1984) ("relevancy is broadly construed at the discovery stage of litigation and a request for discovery should be considered relevant if there is any possibility that the information sought may be relevant to the subject matter of the action"). Denying a party access to potentially relevant discovery constitutes reversible error.[8]

B. Plaintiffs' Own Pleadings, And The Governing Law They Invoke, Show That Discovery Regarding "Government Knowledge" Is Relevant To This Case.

Plaintiffs seek to prohibit virtually all discovery relating to "government knowledge." *See* Plfs. CMO Br. at 7-10. That is improper, however, because the fundamental elements of Plaintiffs' various causes of action require inquiry into areas Plaintiffs would like to declare off limits. Discovery into what the Government knew and when it knew it is probative of, among other things, whether any claims reimbursed based upon published prices were ***false***; whether the Government ***relied***, or justifiably relied, upon published prices as an indication of market prices;

[8] *See Saldana-Sanchez v. Lopez-Gerena*, 256 F.3d 1, 8 (1st Cir. 2001) (finding reversible error when district "court's discovery order was plainly wrong and resulted in substantial prejudice to the aggrieved party"); *Shields v. Twiss*, 389 F.3d 142, 149 (5th Cir. 2004) ("when a party is not given a full and fair opportunity to discover information essential to its opposition to summary judgment, the limitation on discovery is reversible error"); *Travelers Ins. Co. v. Transport Ins. Co.*, 846 F.2d 1048, 1053 (7th Cir. 1988) ("While a district court is vested with broad discretion in denying discovery, it is reversible error if the denial resulted in actual and substantial prejudice to the complaining litigant.").

whether published priced ***caused*** the Medicare and Medicaid programs to pay more than they would have; and whether and/or the extent to which the Government suffered any ***damages***.

Most obviously, Plaintiffs' common law fraud claim requires proof of reasonable reliance. *See* Complaint, ¶ 114 ("The United States acted in justifiable reliance upon Abbott's misrepresentations by making payments on the false claims.").[9] Because fraud claims often turn on the question of reliance, that issue is a focus of discovery. *See Elco Industries, Inc. v. Hogg*, 713 F. Supp. 1215, 1218 (N.D. Ill. 1989) ("evidence concerning plaintiff's knowledge, methods of evaluation, and business experience may well be relevant in establishing whether plaintiff justifiably relied on defendant's statements"). A "person claiming justifiable reliance is required to use his senses, and cannot recover if he blindly relies upon a misrepresentation the falsity of which would be patent to him if he utilized his opportunity to make a cursory examination or investigation." *Collins v. Huculak*, 783 N.E.2d 834, 839 (Mass. App. Ct. 2003). *See also Neptuno Treuhand-Und Verwaltungsgesellschaft Mbh v. Arbor*, 692 N.E.2d 812, 818 (Ill. App. Ct. 1998) ("In determining whether there was justifiable reliance, it is necessary to consider all of the facts within a plaintiff's actual knowledge as well as those that he could have discovered by the exercise of ordinary prudence."). Accordingly, there can be no question that Abbott is entitled to seek discovery that would show "all of the facts within [the Government's] actual knowledge" (*Collins*, 783 N.E.2d at 839) about published prices, and what additional information the Government could have discovered had it utilized its "opportunity to make a cursory examination or investigation." *Neptuno*, 692 N.E.2d at 818.

[9] *See, e.g., Russell v. Cooley Dickinson Hosp., Inc.*, 437 Mass. 443, 458-59 (2002) (fraud plaintiff must prove he "reasonably relied upon the representation as true and acted upon it to his damage"); *Bauer v. Giannis*, 834 N.E.2d 952, 957 (Ill. App. 2005) (the "elements of fraudulent misrepresentation" include "the plaintiff's justifiable reliance upon the truth of the statement").

The discovery is likewise highly relevant to Plaintiffs' FCA claims. Courts have held that the knowledge and actions of Government officials can be directly relevant in FCA cases for many reasons, including the same issues of falsity, reliance, materiality, deception, causation, and damages for which such evidence is relevant here. *See United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 445 (6th Cir. 2005) (if "plaintiff cannot show that the government agency would have acted differently had it known of the omission, 'there is no false claim because [the agency's action] would have occurred regardless of [the defendant's] actions'") (quoting *Rabushka ex rel. United States v. Crane Co.*, 122 F.3d 559, 563 (8th Cir. 1997)); *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) ("Since the [False Claims] Act is restitutionary and aimed at retrieving ill-begotten funds, it would be anomalous to find liability when the alleged noncompliance would not have influenced the government's decision to pay.").[10] All of these issues should be the subject of discovery in this case.

Plaintiffs have no response on the common-law fraud point, and their contention that "evidence about government knowledge is only relevant under the FCA to the extent that it serves to negate a defendant's *scienter*" is just plain wrong. United States' Opposition to Abbott Laboratories, Inc.'s Motion to Dismiss ("Plfs. MTD Br.") at 24. Indeed, Plaintiffs' own filings demonstrate that the knowledge, actions, and decision-making of Government officials is highly relevant to Plaintiffs' claims in this case:

- "***No government payor knew*** of or sanctioned Abbott's conduct as set forth in this Complaint, *i.e.*, its deliberate manipulation of its published prices for certain

[10] *See also United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 (5th Cir. 2003) ("Inevitably, the extent of the government's knowledge is also bound up with whether the claim itself was false.") (citing *United States ex. rel Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)); *United State ex rel. Durcholtz v. FKW, Inc.*, 189 F.3d 542, 544-45 (7th Cir. 1999) ("The government's knowledge effectively negates the fraud or falsity required by the FCA."); *United States v. Medica-Rents*, 285 F. Supp.2d 742, 770 (N.D. Tex. 2003) ("the juxtaposition of the word 'false' with the word 'fraudulent,' plus the meanings of the words comprising the phrase 'false claim," suggest an improper claim is aimed at extracting money the government otherwise would not have paid") (quoting *Mikes*, 274 F.3d at 696).

of its products to induce its Customers to purchase those products." Complaint, ¶ 38.

- "***AWP is used to refer*** to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer who then administers it to a patient." *Id*., ¶ 42.

- "Within the time frames detailed below, Abbott engaged in a fraudulent scheme that ***caused*** the Medicare and Medicaid programs to pay excessive reimbursement to Abbott's customers." *Id*., ¶ 3.

- "The United States ***acted in justifiable reliance*** upon Abbott's misrepresentations by making payments on the false claims." *Id*., ¶ 113.

- "Had the true facts of Abbott's false price reporting as set forth in this Complaint been known to the United States, ***the United States would not have paid for Abbott products***." *Id*., ¶ 114.

- Abbott "***with[eld] information*** and/or purposely provid[ed] misleading information ***that was critical to government decisions*** regarding amounts to pay on claims for Abbott's products." Plfs. MTD Br. at 1.

- "While ***hindsight*** may have shown that some of the data in the compendia were not reliable indicia from which to estimate supplier acquisition costs for certain drugs . . . ." U.S. Amicus at 2.

- "[T]he final rule reflected the ***Secretary's continued belief***, as of 1991, that the wholesale price data published in Red Book and other national drug listings ***generally represented a comprehensive source and indicia of market prices***." *Id*. at 15.

- "The ***Secretary understood*** that Red Book and the other wholesale price guides updated their information monthly, and thus ***believed that the published wholesale prices were a source of acquisition costs*** of *some* physicians and therefore could be used to calculate Part B drug payments." *Id*. at 15.

(Emphases added.) By making these contentions, and then seeking to preclude discovery into government knowledge, Plaintiffs are asking the Court and opposing litigants to take its allegations on faith. The adversary system does not operate that way.[11]

[11] Nor do Plaintiffs' authorities support their contention; those cases merely state that "government knowledge" may be relevant to the question of *scienter*. *See United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) ("government's knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA claim"); *United States ex rel. Kriendler & Kriendler v. United Technologies Corp.*, 985 F.2d 1148, 1157 (2d Cir. 1993) (same); *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 534 (10th Cir. 2000) (same). These cases do not hold that government knowledge is relevant *only* to *scienter*.

C. Plaintiffs' Position Would Preclude Further Inquiry Into Areas Of Government Knowledge That Are Highly Relevant.

Even the publicly-available materials and scant discovery available so far confirm that government knowledge is relevant to multiple aspects of Plaintiffs' claims. These are materials Abbott has obtained *before* any serious discovery in this matter has commenced. Even this preliminary evidence indicates, however, that more discovery would yield information that would be invaluable to Abbott's defense of this suit. By the same token, denial of that discovery would "result[ ] in substantial prejudice to" Abbott. *Saldana-Sanchez v. Lopez-Gerena*, 256 F.3d 1, 8 (1st Cir. 2001) (such a denial is reversible error).

1. Falsity

Plaintiffs contend that the Government meant "AWP" to be the actual average price paid to wholesalers, not published AWPs, and thus any claims not reimbursed based upon the actual average price paid to wholesalers were "false." Abbott, for its part, maintains that the claims submitted by providers were not "false" or "fraudulent" because the Government knew and intended for "AWP" to refer to prices published by the pricing compendia, amounts it knew exceeded acquisition costs. Accordingly, any claims reimbursed based upon published AWPs could not have been "false," as that is exactly what the Government intended and expected.

To challenge Plaintiffs' contentions and prove its case, Abbott seeks discovery on what Government officials believed the term "AWP" meant in statutes and regulations. For example, on July 28, 2000, when 89 members of Congress wrote to HHS Secretary Donna Shalala to oppose her attempts to utilized "revised" AWPs from the Department of Justice, those members of Congress seem to have made Congress' intent on the meaning of "AWP" perfectly clear:

> Thus, Congress in 1997 instructed the Department to base reimbursement for drugs on 95% of AWP, a term widely understood and indeed ***defined*** by Department manuals to reference amounts ***reflected in specified publications.*** Later,

> Congress pegged reimbursement for drugs in the hospital outpatient setting to the same definition of AWP.
>
> It is disturbing that the Department would now seek to circumvent those congressional actions by redefining AWP. We see no basis for such an action in any of our previous legislation, and certainly the Department's unilateral declaration of a new definition of AWP, with no regulatory process, is inappropriate.

(Ex. 6) (emphasis added). *See also Hearing on President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare Before the Senate Committee on Finance*, 105th Cong. 265 (1997) (Ex. 3) (in written response to Congress during deliberations of BBA of 1997, Secretary Shalala states that "the ***AWP is not the average price actually charged by wholesalers*** to their customers," but [r]ather, it is a 'sticker' price set by drug manufacturers and published in several commercial catalogs") (emphasis added); HHC016-0747-48 (Ex. 7) (in 1989 letter, HCFA Associate Regional Administrator notes that while "the term 'average wholesale price' connotes what pharmacies pay for drug products, in the pharmaceutical industry it is commonly understood to be higher than actual costs"). It is ludicrous for the Government to suggest that Abbott is not entitled to explore in discovery the discrepancy between what the Government now says in this lawsuit and what the Government said when Congress was legislating and forbidding Secretary Shalala and the DOJ from reducing reimbursement levels.

Preliminary evidence also suggests that the Government itself believed that claims paid based on AWP were not "false" and that there was no overpayment at all. For example, a former high-ranking CMS official had the following to say in a written response to an HHS-OIG report contending Medicaid "overpaid" for drugs because of reliance on AWPs:

> The OIG concludes that because most states base their reimbursement for drugs on AWPs, inflated AWPs have 'caused Medicaid to overpay for these products.' . . . Since the regulations and relevant state plans authorize payment for drugs based on AWPs, ***regardless of whether those prices are inflated, we have concerns with the statement that states and Medicaid have***

> ***'overpaid' for drugs***. We therefore recommend that the sentences on pages ii (penultimate paragraph, second sentence) and 9 (first paragraph, second sentence) be deleted.

HHS-OIG, OEI-03-01-00010 at Appendix B (Ex. 8) (emphasis added). Again, Abbott is entitled to discover additional evidence along these lines to counter Plaintiffs' position on whether claims reimbursed based upon published AWPs were "false" and whether the Government overpaid.

2. Reliance, Materiality, and Deception

The United States contends it "believed" that published AWPs "generally represented a comprehensive source and indicia of market prices" (U.S. Amicus at 2), and that it "acted in justifiable reliance" when it reimbursed drugs at amounts based on published AWPs. Complaint, ¶ 113. Preliminary evidence, however, indicates that the Government knew that published AWPs were not by any means a reliable source of acquisition costs. For example, in 1989 the HHS-OIG stated:

> [W]e continue to believe that AWP ***is not a reliable price*** to be used as a basis for making reimbursements for either the Medicaid or Medicare programs.

HHS-OIG, A-06-89-00037 (Oct. 1989) (Ex. 9) (emphasis added). It is perhaps not surprising that the Government would want to preclude inquiry into events and understandings like these.

Plaintiffs also profess an unawareness regarding the magnitude of the difference between published AWPs and market prices (the "spread"). *See* Plfs. MTD Br. at 10-11 (referring to "huge spreads" typically "10 or more times higher than the prices which Abbott was actually charging its customers"). Preliminary indications again belie that assertion, particularly as to the type of multi-source drugs at issue here (hereafter, the "Subject Drugs"):

- **1989**: The Senate Special Committee on Aging, chaired by Senator David Pryor, issues a report finding "hospitals, HMOs and nursing homes that contract with wholesalers achieve discounts of up to 99% off AWP." (99% off AWP is equivalent to a 9,900% spread.) Majority Staff Report, Special Committee of

Aging, United States Senate, "Prescription Drug Price: Are We Getting Our Money's Worth?", S. Rep. 101-49, at 11 (1989) (Ex. 10).

- **1992**: In Congressional hearings, testimony by the National Association of Retail Druggists references a 1985 Subcommittee report showing "spreads" as high as 9,467%. *Bills to Amend the Public Health Service Act and the Social Security Act to Establish Limits on Certain Drug Prices: Hearing before the Subcomm. Of Health and Environment of the House Comm. on Energy and Commerce*, 102nd Cong. 280 (1992) (testimony of John M. Rector) (Ex. 11).

- **1993**: GAO issues a report finding that discounts off of AWP ranged from 2% to ***99%.*** GAO/HRD-99-43 at 18 (Ex. 12).

- **1997**: House Committee report accompanying the Balanced Budget Act of 1997 shows Medicare reimbursement for the top 10 oncology drugs ranged from 20% to ***1000%*** of acquisition costs. H.R. Rep. No. 105-149 at 1354 (Ex. 13).

- **1997 – 1998**: HHS-OIG issues reports finding instances were Medicare allowed more than ***10 times*** acquisition costs and ***16 times*** the prices paid by the Department of Veterans Affairs ("VA"). *See* HHS-OIG, OEI-03-97-00290 (1997) at 8 (Ex. 14); HHS-OIG, OEI-03-97-00293 (1998) at 8 (Ex. 15).

These studies show the Government has long known that, for many multi-source drugs, published AWPs had no correlation with acquisition cost. Abbott is entitled to discover whether the Government really did believe that published AWPs were a "comprehensive source and indicia of market prices" (U.S. Amicus at 2) for multi-source drugs, as it now contends, and whether its purported reliance was reasonable under the circumstances. *See Collins*, 783 N.E.2d at 839; *Neptuno*, 692 N.E.2d at 818; *Doe v. Dilling*, --- N.E.2d ---, 2006 WL 2528439, *16 (Ill. App. Ct. Sept. 1, 2006) ("[T]he question of the plaintiff's right to rely on the defendant's representations is one of 'whether, under all the circumstances, plaintiffs had the right to rely on the false representations. This question is to be answered while viewing the representation in light of all the facts of which plaintiff had actual knowledge as well as those of which he 'might have availed himself by the exercise of ordinary prudence.'") (internal citations omitted).

Abbott is entitled to discovery into "all of the facts of which plaintiff has actual knowledge" (*id*.) so that it can make its best case that the Government simply did not rely on

published prices as an indication of market prices for multi-source drugs. And "all of the facts" is not limited to discovery on the "Subject Drugs," as Plaintiffs contend. If, for example, the Government knew that over half of the multi-source drugs tested in an OIG study had acquisition costs less than 50% of published AWPs, that knowledge is relevant to whether the Government really believed – certainly, whether it should have believed – that the published AWPs for the multi-source Subject Drugs were an "indicia of market prices." This is particularly true when the drugs studied were of the same type as (*e.g.*, parenteral drugs), or even chemically equivalent to, the Subject Drugs at issue here.[12]

3. Causation and Damages

Finally, discovery directed to the Government is needed to disprove causation and to challenge damages calculations. If, as the preliminary evidence discussed above demonstrates, the Government knew about "huge spreads" for drugs all along and did nothing, then Abbott's alleged conduct may not have caused the Government's alleged losses. This evidence would be relevant regardless of whether the knowledge and inaction related to the Subject Drugs or some other drug. *See Security Ins. Co. of Hartford v. Trustmark Ins. Co.*, 218 F.R.D. 18, 23 (D. Conn. 2003) (discovery into other transactions unrelated to the action at hand was appropriate in fraud and negligent misrepresentation case, as "practice or custom evidence may be relevant to a determination of whether a misrepresentation was material in the particular instance"); *Marks v. Global Mortgage Group, Inc.*, 218 F.R.D. 492, 497 (S.D. W.Va. 2003) (where plaintiff raised claim of fraud, "evidence of similar transactions was relevant to the plaintiff's claims and

[12] Even more to the point, this very case has put the Government on notice of Abbott's allegedly fraudulent conduct. In 1995, Ven-A-Care served on DOJ a Complaint describing the pricing "spreads" for Abbott's and other manufacturers' drugs. In 1996, Ven-A-Care sent a letter to Bruce Vladeck, the HCFA Administrator, reiterating its allegations against the pharmaceutical industry regarding the "exorbitant reimbursement for infusion and inhalation drugs." R2-0394406-11 (letter), R2-039475-491 (data on Subject Drugs sent with letter) (Ex. 16). Plaintiffs would bar discovery of this letter and Mr. Vladeck's response to it. No rational view of the appropriate scope of discovery in this case could exclude an exploration of why Mr. Vladeck failed to act on this information.

therefore, discoverable"). If Plaintiffs "cannot show that the government agency would have acted differently had it known of the omission, 'there is no false claim because [the agency's action] would have occurred regardless of [the defendant's] actions.'" *A+ Homecare*, 400 F.3d at 445 (quoting *Rabushka*, 122 F.3d at 563).

Even as to the Subject Drugs, there are indications that the Government has had information at its fingertips for years showing wide variations between published and market prices. Abbott has reported its "average manufacturer's price" to CMS/HCFA for each of the Subject Drugs since 1991. And, throughout the claim period, the Government purchased the Subject Drugs directly from Abbott at prices many times lower than published AWPs. Beginning in 1992, Abbott reported a "non-Federal average manufacturer price" to the Government pursuant to legislation limiting the prices charged to VA, DOD and 340B hospitals to 76% of that price. *See* Pub. L. 102-585, Title VI, § 603(a)(1),106 Stat. 4971 (1992); 38 U.S.C. § 8126 (a)(2). Despite having all of this information, and even though it used this information to determine direct prices to the Government (where there was no impact to providers), the Government did not equate Medicare or Medicaid drug reimbursement to market prices.

Abbott is entitled to discover who knew about this pricing information and why they did not lower reimbursement. Abbott also is entitled to develop a record of what existing evidence strongly suggests to be the reason: As with other drugs, Federal and State Governments did not want to lower reimbursement paid to providers. A few examples of the existing evidence demonstrate why further inquiry into this area is directly and critically relevant to this case:

- **1987**: A speech by the Assistant Secretary for Planning and Supervision at HHS notes that many state Medicaid programs "had deliberately held down dispensing fees as a *quid pro quo* for known 'fat' in published wholesale prices." HHC902-1078-89 at 1083-84 (Ex. 17).

- **1997**: In a written response to Congress during deliberations of the BBA of 1997, Secretary Shalala acknowledges that AWP contributed to cross-subsidization of

physicians' services because "physicians should be paid for their professional services and not derive a profit from drugs furnished incident to their professional services." (Ex. 3).

- **2002**: In Congressional hearings, CMS Administrator Thomas Scully observes that drug payments are necessary to "cross subsidize" inadequate Medicare payments for services related to furnishing the drugs. *Subcommittee on Health Hearing on Reimbursement and Access to Prescription Drugs Under Medicare Part B* (Mar. 14, 2002) (testimony of the Honorable Tom Scully) (Ex. 18).

- **2004**: In announcing an increase in payment rates for physicians taking care of Medicare beneficiaries, CMS Administrator Mark B. McClellan states: "We now have new tools to pay appropriately for each drug as well as the valuable services that go along with administering drugs, rather than having an overpayment for one subsidize an underpayment for the other." *Medicare News: Medicare Proposes Payment Rule to Provide New Preventive Benefits and Raise Physician Payments for 2005* (July 27, 2004) (Ex. 19).

Preliminary evidence also suggests that cross-subsidization was the reason why the Medicare program refused to revise its drug reimbursement policies to take account of market prices. When HHS asked Medicare carriers in 2000 to "consider" using revised, "more accurate" pricing information for certain drugs (including the Subject Drugs) developed by the DOJ (HHC006-0103-21) (Ex. 20), 89 members of Congress immediately wrote HHS to protest the action (Ex. 6). HHS withdrew the revised pricing information. AWP034-0046 (Ex. 21). Many state Medicaid programs likewise declined to use the revised pricing information; others reversed implementation of the prices because of provider complaints, or elected to implement the prices for "pharmacy drugs" but not "physician drugs." HHS-OIG, OEI-03-01-00010 (2001) at Appendix A (Ex. 8). Again, evidence regarding what Government officials did in previous, analogous situations is obviously relevant to what they would have done with different pricing information from Abbott. *Security Ins.*, 218 F.R.D. at 23; *Marks*, 218 F.R.D. at 497. Abbott is fully entitled to develop the record on these points.

Preliminary evidence further shows that state Medicaid programs continued using published prices as part of a "negotiation" with providers that had nothing to do with any belief

that published prices – particularly for multi-source drugs – were indicative of market prices. Indeed, HHS' own research shows that "overall compensation to pharmacies in most states is set through a process of political bargaining between pharmacy owners and state legislatures." HHC903-0178 at 0181 (Ex. 22). This sentiment is echoed in email from an Idaho Medicaid official, who noted that interested parties met numerous times "to negotiate reimbursement rates for pharmacies." HHC020-0925-28 (Ex. 23). That perhaps explains why Idaho enacted (and CMS approved) a reimbursement change to AWP–12%, even though everyone had OIG studies showing acquisition costs for multi-source drugs at AWP–69.3%. *Id*. at HHC020-0927.

Testimony from Montana Medicaid officials on this point is also telling. Montana's Pharmacy Program Officer acknowledged that she knew Montana's EAC formula of AWP–10% did not represent "actual acquisition cost," and that Montana paid more than acquisition cost to subsidize insufficient payments to providers. Poulsen Dep. at 57:11-14, 131:21-132:7 (Ex. 24). Moreover, Montana officials received so much negative feedback in March of 2003 from pharmacists and other providers when the officials proposed to modify the EAC formula for generic drugs from AWP–15% to AWP–25% that they decided not to make the change. *See* Preshinger Dep. at 64; Preshinger Dep. Exs. 7, 8 (Ex. 25); Buska Dep. at 382-83 (Ex. 26).

These examples are the tip of the iceberg. Abbott is entitled to broad discovery in this case to prove that federal and state officials deliberately adopted reimbursement formulae knowing full well that they were paying more than the acquisition cost of multi-source drugs, and that they did so for political and policy reasons unrelated to any alleged deception by Abbott.

CONCLUSION

For the foregoing reasons, Abbott respectfully requests the Court to enter the Case Management Order attached as Exhibit 1 and deny Plaintiffs' baseless attempt to restrict the discovery of relevant information.

Dated: October 6, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Brian J. Murray, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES, INC.'S MEMORANDUM IN OPPOSITION TO UNITED STATES' AND RELATOR'S MOTION FOR A COMPREHENSIVE CASE MANAGEMENT ORDER, and supporting exhibits, to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 6th day of October, 2006.

/s/ Brian J. Murray
Brian J. Murray